

DETAILED ACTION

1. Acknowledgement is made of the amendments filed 5/29/2007 and 12/3/2007.

Election/Restrictions

2. Applicant's election without traverse of Species C (claims 15-21, 24, and 31-43) in the reply filed on 12/03/2007 is acknowledged.

Drawings

3. The drawings were received on 5/29/2007. These drawings are acceptable.

Response to Arguments

4. Applicant's arguments filed 12/3/2007 have been fully considered but they are not persuasive.

Regarding Applicants' arguments with respect to claims 31, 32, 35, and 36, Applicants argue that Holupka does not teach imaging a plurality of markers and an in vivo landmark using a first imaging modality, imaging the plurality of markers in a second modality, wherein the in vivo landmark is not imageable in the second modality. However, Examiner asserts and Holupka does teach these limitations. The ultrasound imager does image the fiducial markers as argued by Applicants. However, the actual landmark is not imaged by the x-ray (col. 1, lines 54-56). Thus, the markers are imaged by both modalities but the landmark is not. Therefore, it doesn't matter which imaging modality is labeled as "first" or "second" because the limitations are satisfied either way with one modality being

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able to image the landmark and one modality not being able to image the landmark. Applicants also argue that Holupka does not disclose "monitoring in vivo at least one parameter associated with a body". However, this "parameter" is not further elaborated on. Using the broadest reasonable interpretation, Examiner can then at the very least interpret this "parameter" to be the very location of the landmark as determined using the imaging modalities disclosed by Holupka.

Regarding Applicants' arguments with respect to claims 33, 34, and 37-42, Examiner directs Applicants' attention to the explanation above regarding claims 31, 32, 35, and 36.

5. Regarding Applicants' arguments with respect to claims 15-17, 18-21, and 22-24, a new grounds of rejection has been provided in light of the amended claims.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. **Claims 31, 32, 35, and 36** are rejected under 35 U.S.C. 102(b) as being anticipated by Holupka et al. (U.S. 5,810,007). Holupka et al. teach a method of

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imaging a plurality of markers and an in vivo landmark (prostate gland) in a first imaging modality CT (abstract; col. 3, lines 53-64; col. 4, lines 13-15, and figures 2 & 3); correlating a position of the in vivo landmark relative to at least one of the plurality of markers (col. 3, lines 61-67; fig. 2); imaging the plurality of markers in a second modality (col. 3, line 62), wherein the in vivo landmark is not imageable in the second modality (col. 1, lines 54-56); and determining the position of the in vivo landmark relative to at least one of the plurality of markers based on the correlating (col. 3, lines 61-67).

Specifically regarding claim 31, the actual landmark is not imaged by the x-ray (col. 1, lines 54-56). Thus, the markers are imaged by both modalities but the landmark is not. Therefore, it doesn't matter which imaging modality is labeled as "first" or "second" because the limitations are satisfied either way with one modality being able to image the landmark and one modality not being able to image the landmark.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims **15-21, 24, and 43** are rejected under 35 U.S.C. 103(a) as being unpatentable over Grzeszczuk et al. (U.S.2002/0077543 A1).

Regarding **claims 15, 16, 21, and 24**, Grzeszczuk et al. teach a method comprising: situating a device in a body (para [0056], refer to surgical tools); and identifying a position of the device relative to an internal coordinate system using an imaging technique (para [0056], refer to 'registration'), wherein the internal coordinate system is based on a plurality of markers located in the body having an imageable marker property (para [0052] & para [0056]), wherein identifying comprises identifying the position relative to the at least one of the plurality of markers (para [0053]); and tracking the device over time (abstract)

Grzeszczuk et al. teach the limitations as discussed above but fail to explicitly teach the device being a sensor device. However, Grzeszczuk et al. does teach the device to be a medical instrument inside of a patient (abstract). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of invention to modify Grzeszczuk et al. to teach the medical tool to be a sensor device, as sensor devices are well-known in vivo medical instruments and, by definition, provide the advantage of sensing certain parameters within the body that would be useful for many diagnostic purposes.

Regarding **claim 18**, Grzeszczuk et al. teach the limitations as discussed above but fail to explicitly teach the sensor device having a length less than approximately 26 millimeters. However, it would have been obvious to a person of ordinary skill in the art at the time of the invention to use a sensor device of this size to improve maneuverability of the device when placing it in the human body and since biosensors are also inherently small.

Regarding **claim 19**, Grzeszczuk et al. teach identifying the position relative to an anatomical landmark (para [0052], refer to "skeletal landmark").

Regarding **claim 20**, Grzeszczuk et al. teach the limitations as discussed above but fail to explicitly teach identifying the position of the device relative to an organ. However, Grzeszczuk et al. do teach using anatomical landmarks for image registration. These landmarks would then show up on the display while the medical instrument is being tracked. Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to use certain organs as landmarks as a matter of design choice since different medical procedures would involve different in vivo locations which may cause certain organs with better visibility and proximity to be used for registration purposes.

Regarding **claims 17 and 43**, Grzeszczuk et al. teach the limitations as discussed above but fail to explicitly teach implanting the sensor through injection. However, the methods of implanting a medical sensor will vary based on the type of sensor and the location at which the procedure is performed. Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Grzeszczuk et al. to include injection the sensor as a matter of design choice since the instant application also lacks any mention of a specific advantage of implanting a sensor via injection methods (for example see para [0040] in the Specifications of the instant application).

10. Claims **33, 34, and 37-42** are rejected under 35 U.S.C. 103(a) as being unpatentable over Holupka et al.

Regarding **claims 33 and 34**, Holupka et al. teach that the in vivo landmark is a sensor device (col. 3, lines 50-55; fig. 2) and comprises at least one of the plurality of markers (col. 3, lines 61-67; fig. 2).

Regarding **claims 37, 38, 40, and 41**, Holupka et al. teach a second imaging modality except for the modality of being kV imaging or MV imaging. It is well known in the art that kV imaging and MV imaging provide quality images and excellent localization. It would have been obvious to a person of skill in the art at the time of the invention to use kV imaging or MV imaging as the second imaging modality to achieve quality images with excellent target localization.

Regarding **claim 39**, Holupka et al. teach a first imaging modality except for the modality being MRI. It would have been obvious to a person of skill in the art at the time of the invention to use magnetic resonance imaging as the first imaging modality since it is well known in the art that using magnetic resonance imaging for the first imaging modality to achieve quality images with excellent target localization.

Regarding **claim 42**, Holupka et al. teach a second imaging modality except for the modality being ultrasound when the first imaging modality is magnetic resonance imaging. It would have been obvious to a person of skill in the art at the time of the invention to use magnetic resonance imaging as the first imaging modality since it is well known in the art that using these imaging techniques in the manner provide high quality images and excellent localization.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elmer Chao whose telephone number is (571)272-0674. The examiner can normally be reached on 9am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. C./
Examiner, Art Unit 3737
3/3/2008

/Brian L Casler/
Supervisory Patent Examiner, Art Unit 3737



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EXAMINER

CHIAO, ELMER M

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/664,308

Applicant(s)

SUTHERLAND ET AL.

Examiner

Elmer Chao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-21, 24 and 31-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-21, 24 and 31-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 May 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____